CONFIDENTIAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804 Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 18-op-45090	
The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al Case No. 17-op-45004	

EXPERT REPORT OF HOWARD L. DORFMAN
MAY 10, 2019

I. INTRODUCTION

A. Qualifications

1. My name is Howard L. Dorfman. I am an Adjunct Professor and Distinguished Practitioner at Seton Hall University School of Law located in Newark, New Jersey. Seton Hall University School of Law is a nationally ranked law school with a concentration in health law and compliance where I teach in the Health Law and Healthcare Compliance programs.

2. Previously and beginning in 1978, I served in various senior capacities in national and international companies in the health sector. I served as Vice President and General Counsel at Ferring Pharmaceuticals, Inc. in Parsippany, New Jersey, where I was responsible for all legal matters relating to the U.S. affiliate of the Swiss-based global pharmaceutical and biotechnology company. I also served as Senior Vice President and General Counsel of U.S. operations of Turing Pharmaceuticals, LLC where I supervised all legal activities and served as interim Chief Compliance Officer responsible for developing a compliance blueprint for the company. Previously, I served as Counsel in the Life Sciences group at Ropes & Gray LLP in New York, where I focused on the pharmaceutical, medical device, and biotechnology industries.

3. My areas of professional concentration and experience include Food and Drug Administration ("FDA") regulatory law, fraud and abuse, compliance programs, and risk management processes. Prior to my association with Ropes & Gray, I was chief legal officer of the pharmaceutical division of Bayer Healthcare LLC ("Bayer"), where I was responsible for legal oversight relating to the commercial, regulatory, and compliance

activities of the company's pharmaceutical operations. Before joining Bayer, I worked at Bristol-Myers Squibb ("BMS"), where I first served as Counsel in the litigation department and subsequently as Counsel to the company's U.S. pharmaceutical operations. There I developed the first compliance training program for the Medical Science Liaisons.

4. I have established Office of Inspector General ("OIG") mandated compliance processes and Standard Operating Procedures ("SOPs") at major pharmaceutical and biotechnology companies and start-ups and provided counseling on regulatory, compliance, and risk management issues as well as advising companies on compliance with the Foreign Corrupt Practices Act ("FCPA"). I have lectured and published articles on a range of regulatory, compliance, and product liability issues.

5. I received my B.A. with honors from Yeshiva University and my J.D. from Brooklyn Law School. I am admitted to practice law in New York and New Jersey and a member of the Bar of the United States Supreme Court. My CV is attached as Appendix A to this report.

B. Assignment

6. I have been retained by counsel for Teva Pharmaceuticals USA, Inc. ("Teva USA"), Cephalon, Inc. ("Cephalon"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis LLC ("Actavis LLC"), Watson Laboratories, Inc. ("Watson"), and other affiliates[1] to serve as an expert witness in this case.

[1] Teva USA and Cephalon are referred to as the "Teva Defendants." Actavis Pharma, Actavis LLC, Watson, Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic

7. It is my understanding that that Plaintiffs allege the Teva Defendants engaged in a scheme to fraudulently market opioids. Plaintiffs claim that Defendant manufacturers engaged in unlawful marketing practices towards patients and healthcare professionals ("HCPs") by disseminating "deceptive information about opioids [through] (1) 'Front Groups' with the appearance of independence from the Marketing Defendants; (2) Key Opinion Leaders ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) Continuing Medical Education programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or 'detailers'; and (8) speakers bureaus and programs."[2] In addition, Teva Defendants are accused of falsely marketing Actiq and Fentora for off-label uses.[3] In addition, Teva Defendants are accused of falsely marketing Actiq and Fentora for off-label uses. The focus of the Plaintiffs' allegations against the Teva Defendants is conduct that took place prior to 2013.[4]

8. I have been retained to opine on the following:

   a. Evaluate the health care compliance policies and procedures in place at Cephalon and opine on whether these policies and procedures represented the state of the art

LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida are referred to as the "Actavis Generic Defendants." In addition, I understand that Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") has been named as a defendant based upon the conduct of the Teva and Actavis Defendants, but contests personal jurisdiction. The opinions stated herein as to the Teva and Actavis Defendants also apply to Teva Ltd.

[2] Second Amended Cuyahoga Complaint, May 25, 2018, ¶¶ 319–20; Third Amended Summit Complaint, March 21, 2019, ¶¶ 350–1.

[3] Second Amended Cuyahoga Complaint, May 25, 2018, ¶¶ 819–23; Third Amended Summit Complaint, March 21, 2019, ¶¶ 786–90.

[4] Second Amended Cuyahoga Complaint, May 25, 2018, ¶¶ ; Third Amended Summit Complaint, ¶¶ 216-217, 353, 410, 411, 416, 430, 446, 451, 787-791.

regarding recognized standards for health care compliance programs in the pharmaceutical industry during the relevant time period. Specifically, my opinions will address (1) the policies and standard operating procedures in place at Cephalon with regard to marketing-related activities and programs before signing a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") on September 29, 2008;[5] (2) how these policies changed in the period leading up to and then after the CIA went into effect; and (3) Cephalon's efforts to meet the audit requirements of the CIA.

9. In evaluating a company's commitment to ethical and legal conduct in the marketing of pharmaceuticals, one should examine if the company's efforts track the evolving commercial process, the guidance obtained from enforcement actions taken by government regulators that highlight areas of concern, and a continual updating of internal corporate compliance policies to best reflect continuing developments within the industry. Among other things, I evaluate the extent to which Cephalon complied with industry practices since the issuance of the "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Guidance") by the OIG in 2003.

C. Materials Considered, Compensation and Prior Testimony

10. The opinions expressed in this report are based on my review of the development of compliance requirements by the OIG and other governmental agencies as well as on internal documents relating to existing compliance policies and procedures at Cephalon

[5] Corporate Integrity Agreement, TEVA_MDL_A_06380925-89 (2008).

and Teva USA. I reserve the right to supplement my opinions if additional information becomes available. A list of the documents I and others under my direction considered in forming my opinion is attached as Appendix B.

11. I am being compensated for my expert work on this matter at an hourly rate of $ 475, and, for testimony, at an hourly rate of $575. My compensation is not contingent on the outcome of the litigation. I have not previously testified as an expert witness.

II. SUMMARY OF OPINIONS

12. My opinions in this matter are as follows:

a. I understand that Cephalon had implemented a compliance program and policies as early as 2000.[6] Following the OIG's published guidance on the sales and marketing of pharmaceuticals in 2003, Cephalon began implementing policies and procedures consistent with the OIG Guidance. By at least 2006, Cephalon had put in place a compliance program pertaining to sales and marketing of its prescription medicines, including opioid medicines, that met and often exceeded the practices set forth by the OIG Guidance.

b. The continuing revisions and additions to Cephalon's policies and procedures prior to, in connection with, and after implementation of the CIA, including with respect to promotional interactions with HCPs, further reinforced Cephalon's

[6] *See* Cephalon Corporate Compliance Program (2000), Teva_MDL_A_05508657. This program included guidance on the standards of business conduct, payments to physicians, compliance with federal law, including the FDC Act and the Controlled Substances Act, among other policies. *See id.* However, for purposes of my report, I have focused my analysis on the period after OIG issued its Guidance in 2003.

rigorous compliance program pertaining to sales and marketing of its prescription medicines.

c. Cephalon fully complied with its obligations imposed under the provisions of the CIA and successfully passed all required audits, including evaluations of reportable events, field monitoring programs, and message recall monitoring programs.

III. BACKGROUND

A. OIG Guidance

13. On April 29, 2003, the OIG released its final "Compliance Program Guidance for Pharmaceutical Manufacturers," widely acknowledged to be the single most important development in identifying the critical components of an effective health care compliance program. The OIG Guidance did not outline a "model" compliance program nor was it intended to constitute a compliance program, but instead articulated standards of corporate conduct to assist companies that develop, manufacture, market and sell pharmaceutical drugs in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and related requirements.

14. Furthermore, the OIG Guidance noted three specific risk areas of significant concern to pharmaceutical manufacturers: (1) the integrity of data used by state and federal governments to establish payments under federal health care programs; (2) kickbacks and

other illegal remuneration paid by manufacturers; and (3) compliance with laws regulating drug samples.[7]

15. There are seven key elements to the OIG Guidance as described below.

1. Distribution of written standards of conduct addressing areas of compliance risk

16. The first element of the OIG Guidance recommends "the development and distribution of written standards of conduct, as well as written policies, procedures, and protocols that verbalize the company's commitment to compliance . . . and address specific areas of potential fraud and abuse . . ."[8]

2. Designation of a compliance officer

17. This recommendation calls for "[t]he designation of a compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the board of directors and/or the president or CEO."[9]

3. Implementation of regular training programs

18. The OIG Guidance emphasizes a need for "the development and implementation of regular, effective education and training programs for all affected employees."[10]

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[7] OIG Guidance, p. 6.

[8] Office of Inspector General, "Compliance Program Guidance for Pharmaceutical Manufacturers," ("OIG Guidance"), April 2003, p. 7, available at https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf

[9] OIG Guidance, p. 8.

[10] OIG Guidance, p. 8.

4. Creation of a hotline or other reporting system

19. This OIG Guidance's recommends that companies "creat[e] and maint[ain] an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation."[11]

5. Utilization of audits or risk evaluation techniques

20. This OIG guidance emphasizes the need for "[t]he use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems."[12]

6. Policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs

21. This recommendation further calls for "the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements."[13]

7. Investigation procedures for identified instances of noncompliance

22. The OIG Guidance also recommends "[t]he development of policies and procedures for the investigation of identified instances of noncompliance or misconduct. These should

[11] OIG Guidance, p. 8.

[12] OIG Guidance, p. 8.

[13] OIG Guidance, p. 8.

include direction regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances."[14]

23. It is important to note the focus of the OIG Guidance is to help pharmaceutical companies "in developing and implementing internal controls and procedures that *promote adherence to applicable statutes, regulations and requirements of the federal health care programs*..." (Emphasis added).[15] The use of the term "promote" in the context of adherence indicates the OIG's realization that any compliance program, no matter how carefully developed, can promote appropriate conduct, but cannot totally eliminate potential violations of the health care statutes, regulations and requirements. The inclusion of such provisions as an effective auditing and monitoring function as part of a company's compliance program speaks to the recognition that inappropriate conduct may arise, requiring diligence in identifying examples of improper conduct, determining the root cause of the violation, and development of remediation measures to reduce the risk of such activity continuing.

24. In fact, the OIG Guidance itself explicitly recognizes such limitations in advocating for the development and implementation of a rigorous compliance function. After stating several of the benefits of a compliance program, the OIG Guidance states: "The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer. However, a good faith effort by the company to comply with applicable statutes and regulations as

[14] OIG Guidance, pp. 8-9.

[15] OIG Guidance, p. 2.

well as federal health care program requirements, demonstrated by an effective compliance program, *significantly reduces the risk of unlawful conduct*....” (Emphasis added).[16] Measured by the standards set out by the OIG, Cephalon meets and often exceeds the recommendations of the OIG Guidance.

B. 2008 Settlement

25. In 2008, Cephalon and the Department of Justice (“DOJ”) entered into a settlement of an off-label promotion case. Cephalon entered into a misdemeanor plea for one count of misbranding through off-label promotion of three prescription medicines (which included Actiq) from January 2001 to October 2001.[17] The conduct that gave rise to the settlement took place prior to the OIG issuing its guidance at a point in time when the compliance function was yet to be developed as an integral part of the pharmaceutical corporate structure. As a part of the settlement, Cephalon and the OIG entered into the Corporate Integrity Agreement in order to fulfill the OIG’s compliance requirements.

C. Corporate Integrity Agreement

26. The CIA was a five-year agreement effective from September 29, 2008 to September 29, 2013.[18] The agreement provided direction for upgrading Cephalon’s existing compliance program and imposed a number of additional requirements, including annual reporting and oversight by an Independent Review Organization (“IRO”).

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[16] OIG Guidance, p. 5.

[17] Misdemeanor Guilty Plea, at ¶ 1, 6A, available at https://www.justice.gov/civil/file/892071/download.

[18] Corporate Integrity Agreement (“CIA”), TEVA_MDL_A_06380925-89, at TEVA_MDL_A_06380926, TEVA_MDL_A_06380932, TEVA_MDL_A_06380940, TEVA_MDL_A_06380945, TEVA_MDL_A_06380950 (2008).

27. Annual reports documented compliance progress from October 1 to September 30 of the following year. Information typically included in these reports covered updates to the chief compliance officer job description, policy updates, a report on suspected reportable events, an independent reviewer report and related corrective action plans, a summary of annual message recall studies, a summary of sales force monitoring programs, relevant FDA communication, training summary and statistics as well as disclosures related to federal health care programs.[19]

1. Independent Review Organization

28. Common to all CIAs, Cephalon was required to retain an IRO to assist Cephalon in "assessing and evaluating its Promotional and Product Services Related Functions."[20] The IRO was to perform an analysis of how Cephalon received and responded to requests for information from HCPs about non-FDA approved uses of Cephalon's products and the form and content of information disseminated by Cephalon in response.[21] The IRO would also evaluate Cephalon's call plans developed by the company's sales function and the call plan review process to determine whether Cephalon failed to follow its own criteria of policies and procedures relating to call plans or the review of call plans.[22]

[19] See, for example, CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00562290.

[20] CIA, TEVA_MDL_A_06380925-89 at TEVA_MDL_A_06380940 (2008).

[21] CIA, § III.D.1.b. Providing such medical information to HCPs has long been recognized by the Food and Drug Administration as a critically important role for pharmaceutical manufacturers in providing important information to help guide therapeutic decisions.

[22] CIA, § III.D.1.b; Report on Independent Review Organization Engagement Procedures, Findings and Recommendations in CIA Annual Report Year 1, TEVA_MDL_A_00561910 (2009).

2. Reportable Events

29. The CIA required Cephalon to report events that involved "matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized."[23]

3. Field Force Monitoring Program

30. The Field Force Monitoring Program was established to evaluate and monitor sales representatives' interactions with HCPs and to identify potential off-label promotional activities. This monitoring was carried out through direct field observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs were consistent with Cephalon policies. The observations would be full-day ride alongs with field sales representatives, randomly selected by Cephalon throughout the year. These evaluations would cover each therapeutic area and actively promoted product throughout the United States.[24]

4. Message Recall Monitoring Program

31. The Message Recall Monitoring Program was another program established to identify potential off-label promotional activities by the sales representatives. This program entailed the analysis of studies generated by an independent survey entity reflecting

[23] CIA, TEVA_MDL_A_06380925-89, at 06380946 (2008).

[24] CIA, § III.K.

physician recall of marketing messages delivered by Cephalon's sales force.[25] The findings of the message recall studies were again summarized in the annual reports to the OIG and included any off-label findings, a description of the actions Cephalon took or planned to take in response to any off-label findings, and the underlying records of the detailing interactions.[26]

IV. OPINION #1: CEPHALON IMMEDIATELY ADDRESSED AND IMPLEMENTED INTERNAL POLICIES AND PROCEDURES CONSISTENT WITH THE PRINCIPLES FIRST ENUNCIATED BY OIG IN 2003. BY AT LEAST 2006, CEPHALON INSTALLED A SALES AND MARKETING COMPLIANCE PROGRAM THAT MET AND OFTEN EXCEEDED THE STANDARDS SET FORTH BY THE OIG GUIDANCE.

32. Following the issuance of OIG Guidance in 2003, Cephalon successfully enhanced and refined its existing policies to incorporate the new provisions suggested by OIG Guidance. A review of internal Cephalon documents regarding policies developed in the wake of the OIG Guidance reveals a consistent effort to maintain a rigorous compliance program. By at least October 2006, Cephalon had put in place a compliance process that met and often exceeded each of the principles set forth by the OIG Guidance.

33. The policies and procedures developed and implemented by Cephalon, as discussed in greater detail below, address the most significant concerns consistently expressed by OIG relative to the societal benefits to be derived from an effective compliance program and the methods by which these policies and procedures can reduce the risk of prosecution. In my opinion, these are (1) Does the activity have the potential to interfere with or undermine the independent clinical judgement of a HCP in determining the appropriate

[25] CIA, § III.J.

[26] CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00561764 (2009).

course of therapy? (2) Does the activity have the potential to increase reimbursement costs to the federal health care programs? (3) Does the arrangement have the potential to increase overutilization or inappropriate utilization of the company's therapies? (4) Does the arrangement raise issues and concerns regarding patient safety or quality of care?[27]

A. Hiring of a Chief Compliance Officer and Reorganization of Global Compliance Committee

34. In May 2004, Cephalon hired a Chief Compliance Officer ("CCO") to oversee all compliance initiatives.[28] Cephalon then changed its corporate reporting structure so that the CCO reported directly to the CEO and Audit Committee, rather than the General Counsel.[29] Compliance with this particular OIG recommendation speaks to Cephalon's commitment to a robust compliance function. Any reporting arrangement that could impede the free flow of information from the CCO, such as having the CCO report to the General Counsel or Chief Legal Officer, could lead to assertions of privilege that could delay timely reporting of compliance-related issues and negatively affect the compliance program in such areas as auditing, monitoring, and investigations.

35. In addition, Cephalon revamped its Global Compliance Committee by adding new members and clarifying its purpose via a new charter, which set forth the committees' directives, including, but not limited to, "provid[ing] guidance and support to the Chief Compliance Officer and the Global Compliance Program," "support[ing] Cephalon's

[27] OIG Guidance, p. 15.

[28] 2004 Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377163 (July 29, 2004).

[29] 2004 Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377164 (July 29, 2004).

compliance effort across all departments and functions," and "foster[ing] and support[ing] ethical conduct by Cephalon employees and agents."[30]

36. Further, while Cephalon had a committee in place since 1999 to review and approve promotional, advertising, and labeling materials for FDA products,[31] Cephalon implemented a number of enhancements in the 2008 and 2009 time period, including implementing a formal policy that outlines the steps that any promotional material must go through prior to being approved for use.[32] This included review and approval by Cephalon's established Promotional & Disease Review Committee ("PDRC"). All promotional materials – *i.e.*, any material that could be used in promotion with HCPs, among other content – needed to be reviewed by the PDRC (which was later changed to the Promotion and Advertising Review Committee ("PARC")). [33]

37. The PDRC was tasked with ensuring each piece of promotional material was accurate and not misleading; made claims about a product only when properly medically substantiated; accurately reflected the balance between risks and benefits; was consistent with other applicable FDA requirements; and reflected appropriate taste consistent with

[30] Charter of Cephalon's Global Compliance Committee, TEVA_MDL_A_00819644-45, at TEVA_MDL_A_00819644 (January 2009).

[31] In 1999, prior to Cephalon ever selling an opioid product, Cephalon created the Promotional Review Committee to review and approve promotional, advertising, and labeling materials for FDA-approved products. *See* Review and Approval of Promotional Materials (SOP-0348-R01), Teva_MDL_A_04785055-62. The name of this committee later changed to the Promotional & Disease Review Committee, which is referenced in Cephalon's March 2007 Policy on Promotional Materials and Activities. That policy makes clear that all promotional materials and branded press releases, must be submitted to the PDRC for review and approval and that sales representatives may only use PDRC approved materials when detailing a Cephalon product. Policy on Promotional Materials and Activities, TEVA_MDL_A_01251780-89.

[32] Promotional Review Process (GPO-110), TEVA_MDL_A_00552513-25 (Jan. 26, 2009).

[33] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923235, (Dec. 16, 2008); Cephalon created the Promotional Review Process GPO-110 to outline the PDRC review process.

Cephalon's values.[34] Additionally, many of Cephalon's promotional materials were sent to the Food and Drug Administration's Division of Drug Marketing, Advertising and Communications ("DDMAC") for review and approval prior to distribution.[35]

38. PDRC reviewers consisted of members from four functional areas, each with a unique responsibility. These areas included: Marketing, Regulatory, Legal, and Medical.[36] Each reviewer was expected to provide formal feedback with supporting rationale and approval in their functional area. Reviewers could, however, make informal comments outside their functional area.[37] When PDRC review was necessary, a tracking number and form was required for the project; this allowed Cephalon to easily monitor a document as it was developed into final form and to ensure that only documents approved by the PDRC were used in promoting the company's products.[38]

39. These steps by Cephalon meet or exceed all of the recommendations of the relevant elements within the OIG Guidance.

[34] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923240, (Dec. 16, 2008).

[35] Promotional Review Process (GPO-110), TEVA_MDL_A_00552513-25 (Jan. 26, 2009).

[36] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923239, (Dec. 16, 2008).

[37] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923240 (Dec. 16, 2008).

[38] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923245, (Dec. 16, 2008).

B. Revision to Code of Conduct and Development of Written Compliance Polices Regarding Marketing and Sales

40. In May 2004, Cephalon revised its Code of Conduct to cover a wide array of compliance issues, including those pertaining to the marketing and sale of its prescription medicines. The revised Code of Conduct reinforced many of Cephalon's existing policies. Specifically, it prohibited violations of FDA regulations and company policies and required employees to report violations through various mechanisms, including an anonymous compliance hotline.[39] Cephalon required all employees to certify annually that they had read, understood, and would abide by the terms of the document.[40]

41. ***The 2004 Sales Policy Handbook***. In 2004, consistent with its commitment to ensure compliance with applicable legal requirements and the OIG guidance, Cephalon developed a Sales Policy Handbook ("2004 Handbook") which contained ten compliance ground rules and 11 specific policies concerning the sales and marketing of Cephalon's products.41 The Handbook outlined internal compliance standards related to off-label promotion and fraud and abuse/anti-kickback concerns with the goal of "provid[ing] enhanced guidance to [Cephalon employees] on appropriate promotional practices."42 The Handbook emphasized that Cephalon was committed to upholding more conservative compliance standards than those set by existing legal requirements, reminding employees to "adhere to the Company standard[s] notwithstanding the fact the

[39] 2004 Cephalon Code of Conduct, TEVA_MDL_A_09624030-698, at TEVA_MDL_A_09624194 and TEVA_MDL_A_09624196 (2004).

[40] 2004 Cephalon Code of Conduct, TEVA_MDL_A_09624030-698, at TEVA_MDL_A_09624196 (2004).

[41] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794294 (Oct. 2004).

[42] 2004 Annual Compliance Update (December 16, 2004), which was part of the December 16, 2004 Board of Directors Meeting, TEVA_MDL_A_00667543-754, at TEVA_MDL_A_00667613.

law may permit 'more aggressive' conduct."43 Specifically, the 2004 Handbook called on employees to "[k]now and follow the letter and spirit of the Compliance Policies applicable to your job and our industry," "avoid conduct risking involvement in any unlawful practice," and "report violations, even in awkward and uncomfortable situations," among other requirements.[44]

42. In particular, the 2004 Handbook emphasized compliance "with all applicable laws and regulations" and adherence "to good faith and professional standards in the conduct of its marketing and promotional activities."[45]

43. In addition to providing an overview of the laws and standards that affect the sales and marketing of Cephalon Products, the 2004 Sales Policy Handbook references 11 specific policies that were in place at the time and for which sales representatives were required to follow. These policies include: (1) Policy on Advertising and Promotional Materials and Activities,[46] (2) Policy on Identifying Called on Universe of Physicians in Connection with Promotional Activities,[47] (3) Policy Regarding Medical Information Request Forms,[48] (4) Policy on Gifts, Meals and Entertainment for Physicians and Other Healthcare Practitioners,[49] (5) Policy on Promotional Meetings,[50] (6) Policy on

[43] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794287 (Oct. 2004)

[44] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794292 - TEVA_MDL_A_04794293 (Oct. 2004).

[45] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794287 (Oct. 2004).

[46] TEVA_MDL_A_11892858-61.

[47] TEVA_MDL_A_11892862-64.

[48] TEVA_MDL_A_11892865-70.

[49] TEVA_MDL_A_11892871-74.

[50] TEVA_MDL_A_11892876-82.

Preceptorships,[51] (7) Policy on Funding to Support Independent Third-Party Educational or Scientific Meetings,[52] (8) Policy on Grants or Support that Are not for Independent Medical Education,[53] (9) Policy re: Sample Management,[54] (10) Policy re: Employeee Reporting of Adverse Events, Product Complaints, Tampering Adulteration and/or Diversion,[55] and (11) Policy on Providing Reimbursement Information to Customers.[56]

44. These policies provide specific guidance and make clear the boundaries of appropriate versus inappropriate promotion and conduct. By way of a few examples:

45. *Promotional Activity.* Among other direction, the 2004 Policy on Advertising and Promotional Materials and Activities makes clear that all promotional materials must be reviewed and approved by Cephalon's Promotional Review Committee and that "no Cephalon sales representative may promote any unapproved Company product or approved product for an unapproved use."[57] In addition, Cephalon required its sales and marketing employees to discuss Cephalon products "in conformity with the approved product labeling, which includes, among other areas, approved indications, contraindications, warnings, and mechanism of action . . ." and provide "appropriate information and education to physicians through permissible means, including with

[51] TEVA_MDL_A_11892883-86.

[52] TEVA_MDL_A_11892887-99.

[53] TEVA_MDL_A_11892900-03.

[54] TEVA_MDL_A_11892875.

[55] TEVA_MDL_A_11892904-06.

[56] TEVA_MDL_A_11892838-39.

[57] TEVA_MDL_A_11892858-61, at TEVA_MDL_A_11892858.

respect to clinical studies regarding our products."[58] As part of that instruction, the 2004 policy reaffirms that off-label discussions are not prohibited — "[s]ales representatives may not transition from one permitted topic (such as approved indications) to another permitted topic or action (such as handing a reprint of an article to a physician) in a manner which improperly suggests that Company products are safe and effective for indications other than those in our approved labeling."[59]

46. *Policy on Funding to Support Independent, Third Party Educational or Scientific Meetings (e.g., CMEs).* In its 2004 policy concerning support for independent third party organizations, among other directions, Cephalon makes clear that the program provider must maintain control over the content of the program and that "Cephalon employees may not prepare scripts for speakers, target points for emphasis, or otherwise attempt to influence the content of the program."[60] The policy prevents any influence by Cephalon over any medical education.

47. *Grant Policy.* In addition to a policy governing independent medical education grants, Cephalon also had a policy for grants or support that are not for independent medical education.[61] This policy makes clear that "no grant or contribution can be made to reward or influence any individual practitioner's prescribing or an institution's formulary treatment for Cephalon's products."[62]

[58] Id.

[59] TEVA_MDL_A_11892858-61, at TEVA_MDL_A_11892859..

[60] TEVA_MDL_A_11892887-99, at TEVA_MDL_A_11892887.

[61] TEVA_MDL_A_11892900-03, TEVA_MDL_A_11892900.

[62] Id.

48. *Promotional Speakers*. In line with recommendations from the OIG Guidance, Cephalon instituted and maintained a robust policy regarding the selection, contracting, and training of its promotional speakers. As early as 2004, the Company had put in place an identification and approval process for potential additions to its Speaker Bureau to ensure speakers are actively involved in patient care, have extensive experience in the relevant disease state or therapeutic area, have experience with the Cephalon product in the therapeutic area about which the speaker will lecture, and are not listed on the OIG exclusion list.[63] In addition, the policy required all speakers to complete live trainings on subjects including, but not limited to, product labeling, approved slide kits, FDA and OIG regulations, and risk minimization plans before giving presentations on Cephalon products.[64]

49. These are just a few examples of the clear guidance provided by Cephalon in its 2004 compliance policies. Based on my many years of experience in developing and evaluating compliance programs for adherence to OIG guidelines, the policies set forth in the 2004 Sales Policy Handbook were consistent with industry practices at that time for well-designed, written policies to address compliance with the various laws and regulations that govern the sale and promotion of pharmaceutical products.

50. ***Updates to the Sales Policy Handbook and Other Policy Updates***. Cephalon reviewed and revised its policies in 2006 when it updated its Sales Policy Handbook and related policies.[65] It again reviewed and revised its policies and issued another update in June

[63] Cephalon Speaker Bureau Policy (2004), TEVA_MDL_A_00552396-420, at TEVA_MDL_A_00552396.

[64] Cephalon Speaker Bureau Policy (2004), TEVA_MDL_A_00552396-420, at TEVA_MDL_A_00552396.

[65] 2006 Sales Policy Handbook, TEVA_MDL_A_01251767-77, at TEVA_MDL_A_01251775 (Oct. 2006).

2007 when Cephalon released its Marketing Policy Handbook.[66] The fact that Cephalon revisited, reviewed, and revised is sales and promotional policies further demonstrates that Cephalon was committed to following OIG Guidance's recommendations and that Cephalon's policies were meeting or exceeding those recommendations. Indeed, Cephalon continued to review and refine its policies throughout this period and leading up to the implementation of the CIA, as well as afterwards. By way of a few examples:

51. *Promotional Activity.* In Cephalon's March 2007 update to the Policy on Promotional Materials and Activities, Cephalon provides a more detailed guide to maintain compliance during sales calls, both in general and in regards to specific products. The March 2007 policy makes clear that "if the HCP raises an off-label use… the sales representative should steer the conversation away from the specific disease state identified by the HCP and instead focus on the attributes and clinical benefits of the Cephalon product," and "[a] sales representative should use the [Medical Information Request Form] process… for questions initiated by the HCP that are off-label."[67] The March 2007 policy also contained sales call guidance specific to Fentora, noting that a sales representative must focus the body of his or her call on breakthrough cancer pain.[68]

52. *Gifts, Meals, and Entertainment.* Likewise, the October 2006 update to the Policy on Gifts, Meals, and Entertainment for Physicians and other Health Care Practitioners

[66] Marketing Policy Handbook (June 2007), TEVA_MDL_A_00552840-49.

[67] Policy on Promotional Materials and Activities (March 2007), Teva_MDL_A_06880605-14, at Teva_MDL_A_06880606. The Medical Information Request Form ("MIRF") is a form that sales representative provide to HCPs in response to an unsolicited request for off-label information. The form would document the unsolicited nature of the request, identify the HCP's specific request, and allow monitoring and follow-up as appropriate.

[68] Policy on Promotional Materials and Activities (March 2007), Teva_MDL_A_06880605-14, at Teva_MDL_A_07880612.

provides additional detail and guidance on the policy concerning gifts, meals, and entertainment for physicians and other HCPs so that it continued to meet industry best practices. Key tenets included balancing the volume of in- and out-of-office meals, moderating the cost per attendee of meals and entertainment, and ensuring all meals and events remain centered on appropriate discussion of the relevant product.[69]

53. Cephalon re-iterated its compliance policy with respect to meals and entertainment in its Good Business Practices Field Guide ("GBP") and continued to emphasize the company's "We don't buy business," approach.[70] For example, the GBP makes clear that sales employees should not target high prescribers with expensive meals and entertainment. In fact, the GBP states that employees faced "with a choice of two options: a more expensive choice and a less expensive choice . . . are expected to choose the less expensive option."[71]

54. *Promotional Speakers.* Cephalon updated its Speaker Bureau Policy in June 2007. To ensure continued compliance, the updates reinforce that once a speaker is selected as a member of the bureau, Cephalon promotional speakers are held to rigorous standards, particularly with regards to off-label promotion. Among other direction, the policy makes clear that all speaker materials must be approved by the PDRC committee, that speakers are not permitted to make any changes to any slides in the approved slide-deck,

[69] Policy on Gifts, Meals, and Entertainment for Physicians and other Health Care Practitioners (October 2006), TEVA_MDL_A_04756815-21.

[70] The Good Business Practice Field Guide (June 2008), TEVA_MDL_A_00552305-63. The GBP was developed by the CNS and PCS Sales Organization to provide guidance and clarify expectations for specific business behavior in the field. *Id.* The fact that Cephalon chose to reinforce and elaborate on its formal policies through the GBP is another factor that shows Cephalon was meeting or exceeding OIG guidelines.

[71] The Good Business Practice Field Guide (June 2008), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_0552331.

and that all speaker programs must begin with a substantive "on-label" discussion. The policy also provides direction on how a speaker may appropriately answer an unsolicited off-label question.[72]

55. ***Good Business Practices Field Guide ("GBP").*** Cephalon enhanced and reinforced its written policies by issuing a Good Business Practices Field Guide in June 2008, which provides additional detail, context and explanation of its formal policies. Specifically, the GBP provides further guidance and clarifies expectations for specific business behavior in the field by sales representatives. The GBP provides comprehensive requirements for sales representatives regarding: (1) promotional activities;[73] (2) meals and gifts;[74] (3) speaker programs;[75] (4) targeting and call activity;[76] and (5) Reimbursement and Managed Care.[77] Each section of the GBP contains "recommended" and "not recommended" strategies, as well as Q &A's on some of the most salient compliance issues.

56. ***US Sales and Marketing Policy***. In July 2008, Cephalon issued a U.S. Sales and Marketing Policy.[78] The policy is applicable to all U.S. Cephalon employees whenever

[72] Marketing Speaker Bureau (CSP) Policy (June 2007), TEVA_MDL_A_00954145-69.

[73] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552316-20 (June 2008).

[74] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552323-34 (June 2008).

[75] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552332 and TEVA_MDL_A_00552336-50. (June 2008).

[76] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552351-54 (June 2008).

[77] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552355-63. (June 2008).

[78] U.S. Sales and Marketing Policy, TEVA_MDL_A_00552786-818 (July 2008).

they are interacting with healthcare professionals and organizations. The policy makes clear that failure to comply with the letter or spirit of the company's policy may lead to disciplinary action including termination. The two basic principles of the policy are: (1) "Our promotional messages are on-label, truthful and fair balanced," and (2) "We do not buy business." The 2008 US Sales and Marketing Policy reiterates the rules for and provides additional guidance to employees regarding promotional activities, meals and gifts, hiring health care professionals, third-party grant requests, and reimbursement support.[79]

57. Ultimately, by 2008, Cephalon had adopted and implemented a number of policies, including those listed in Appendix C.

58. There is little doubt that Cephalon acted in a timely manner to address compliance standards following the release of the OIG Guidance and, in fact, did do so. The continuing revisions and additions to the Cephalon policies and procedures, including with respect to promotional interactions with HCPs, demonstrated Cephalon's commitment to monitor and address evolving compliance issues.

C. Establishing and Maintaining a Compliance Hotline and Enforcement of Compliance Policy

59. Cephalon introduced a compliance hotline in early 2003 that allowed employees to report possible compliance violations either on a named or anonymous basis.[80] To encourage reporting and reduce the risk of retaliation, Cephalon engages a third-party vendor to be

[79] U.S. Sales and Marketing Policy, TEVA_MDL_A_00552786-818 (July 2008).

[80] Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377165 (July 29, 2004).

the first line of response for hotline calls.[81] The company also retains a log of each complaint containing the reporting employee's name (if not anonymous), investigator name, date of incident report, a brief statement of the incident, the resolution or remediation, and the date of incident close.[82]

60. According to the log of complaints provided by Cephalon, there were approximately eighteen incidents related to Actiq and thirteen related to Fentora between 2003 and 2008. Although most of these incidents resulted in findings of no improper conduct or a written warning, the log shows that Cephalon investigated each complaint promptly with an eye toward diligent enforcement. For example, in March 2005, a DEA agent alleged that a physician had remarked that a Cephalon sales representative indicated "it was okay to use Actiq for rheumatoid arthritis and degenerative joint arthritis."[83] Within twenty-four hours of receiving the complaint, Cephalon contacted the physician who then "indicated that he did not make these statements and that he believes Cephalon's promotion has been consistent with the label."[84]

61. In another case, a pharmacist contacted the hotline in December 2007 to report that a representative had provided an Actiq placebo to a physician even though placebos should have been used or destroyed prior the end of 2006.[85] Within a week, Cephalon had

[81] Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377165 (July 29, 2004).

[82] TEVA_MDL_A_06616796-855

[83] TEVA_MDL_A_06616796-855, at 6806.

[84] Id.

[85] TEVA_MDL_A_06616796-855, at 6854.

contacted the prescribing physician and pharmacist and discovered that the physician had actually provided the placebo, not the representative.[86]

62. These and other hotline entries unrelated to Actiq or Fentora illustrate Cephalon's "development of policies and procedures for the investigation of identified instances of noncompliance and misconduct" as well as "initiation of appropriate corrective action and preventive measures. . .," as set forth in the OIG Guidance.[87] For example, in August 2004, Cephalon placed an employee on 60-day probation and long-term monitoring for making "certain promotional claims . . .which were not consistent with FDA label [sic]."[88]

63. In another incident involving a complaint that a sales representative had made off-label claims, Cephalon mandated compliance counseling from the Chief Compliance Officer and the representative's direct manager, sent a memo "detailing the representative's deficiencies and further indicating violations of Cephalon policies would subject the representative to additional discipline," and required the representative to retake internal compliance training as well as "ride with the area trainer for additional training."[89] In another case, Cephalon terminated a representative following investigation and confirmation of a serious violation of the Policy on Meals, Gifts, and Entertainment.[90] This again demonstrates Cephalon's compliance with the OIG Guidance during the period between 2003 and 2008.

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[86] Id.

[87] OIG Guidelines, p. 8.

[88] TEVA_MDL_A_06616796-855, at 6796.

[89] TEVA_MDL_A_06616796-855, at 6799-6800.

[90] TEVA_MDL_A_06616796-855, at 6801.

D. Establishing and Maintaining Effective Training Programs

64. As early as 2004, the Cephalon Legal Department had implemented an Investigations Training Handbook designed to acquaint sales management with the requirements of proper compliance and employment investigation.[91] In May 2004, at the National Manager Meeting, the Legal Department used this Handbook to train all sales managers on appropriate promotional and detailing practices so that these managers could train their representatives at the June 2004 Plan of Action meeting.[92]

65. Over the same period, Cephalon implemented a company-wide Learning Management System ("LMS") for training and policy dissemination to all employees including Sales. LMS rolled out training materials (including compliance policies and procedures) to all employees and tests for employees to gauge their comprehension of such materials.[93] Furthermore, LMS simplifies the tracking process by which the company could identify employees with incomplete training.[94] In a similar vein, LMS tracks employees' roles during their tenure such that it would automatically notify an employee of additional training requirements as a result of a change in position.[95]

66. In 2005, Cephalon also launched Ethics Connect, an electronic learning management system of training modules for all employees, including the sales force. To fulfill their

[91] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81 (July 29, 2004).

[92] Id.

[93] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377166 (July 29, 2004).

[94] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377166 (July 29, 2004).

[95] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377166 (July 29, 2004).

training requirements, employees have to complete a required number of modules per year.[96] In order to fulfill their Ethics Connect requirements, employees also have to sign electronically an acknowledgment stating they will comply with the company's Code of Conduct and Standards of Business Conduct.[97]

67. In April 2006, Cephalon's Sales Training and Development Department updated their training processes to ensure sales employees understood compliance requirements associated with product promotion.[98] The updated training requires newly-hired sales employees to complete a three-phase training program on product information, department policies, and compliance procedures.[99] Also, it mandates all sales employees to score 90 percent or higher on an annual certification exam testing knowledge of the sale and effective use of Cephalon products. Employees scoring under 90 percent are not allowed to promote company products.[100]

68. In June 2007, as part of the Marketing Speaker Bureau (Certified Speaking Professionals ("CSP")) Policy, all Cephalon speakers are required to go through training on compliance with FDA and OIG regulations. In particular, the company trains speakers on the appropriate ways to address unsolicited off-label questions posed during Q&A portions of speaker programs. The published CSP policy emphasizes that doctors do not have to

[96] Cephalon Newsletter (Summer 2005), TEVA_MDL_A_08272952.

[97] Standards of Business Conduct, TEVA_MDL_A_06880695-710, at TEVA_MDL_A_06880697 (Oct. 4, 2007).

[98] Training Process for Members of the Sales Organization (SOP-0001044), TEVA_MDL_A_01249224-28 (April 6, 2006).

[99] Training Process for Members of the Sales Organization (SOP-0001044 TEVA_MDL_A_01249224-28 (April 6, 2006).

[100] Training Process for Members of the Sales Organization (SOP-0001044), TEVA_MDL_A_01249224-28 (April 6, 2006).

answer any off-label questions, but recognizes a speaker may provide a verbal answer to an off-label question as long as the speaker believes he or she can provide an objective, scientifically accurate, and balanced response. However, the training materials within the policy make clear that Cephalon sales representatives are not to recommend or suggest the speaker address any off-label uses of the product.[101]

69. A Cephalon presentation titled "Understanding FDA Regulations" describes how Cephalon has long been committed to compliance by focusing on FDA regulations and states "[e]very year our company objectives begin with compliance – all activities must be in compliance with laws and Company Policies." The presentation also provides an overview of the Food, Drug & Cosmetic Act and the "very specific, limited circumstances" when information about off-label uses is appropriate.[102] The presentation explains that manufacturers may be able to provide additional information about their products to further scientific exchange (such as MIRFs for unsolicited inquiries and presentations of studies at scientific forums). It further instructs that when the physician raises questions about off-label product use, the representative should make full use of MIRFs, refer the physician to colleagues with knowledge in the area being questions, and make appropriate use of WLF reprints. Representatives should not imply that the product is indicated for something that it is not.[103]

[101] Marketing Speaker Bureau (CSP) Policy, TEVA_MDL_A_00954145-69 (June 2007).

[102] "Understanding FDA Regulations," TEVA_MDL_A_02724063.

[103] "Understanding FDA Regulations," TEVA_MDL_A_02724063. The Washington Legal Foundation ("WLF") decision held that FDA's restriction preventing pharmaceutical companies from providing off-label information violated the provisions of the First Amendment applicable to protected Commercial Free Speech. This opinion was later formalized in two FDA Guidance documents and justified the dissemination of appropriate scientific information to HCPs. Accordingly, Cephalon developed a procedure whereby an HCP could obtain a medical reprint from a sales representative.

70. The policies and procedures developed and implemented by Cephalon address the most significant concerns consistently expressed by OIG. As stated elsewhere, these concerns manifest themselves in the following goals: eliminating the potential to interfere with or undermine the independent clinical judgement of an HCP in determining the appropriate course of therapy; eliminating the potential to increase reimbursement costs to the federal health care programs; eliminating the potential to increase overutilization or inappropriate utilization of the company's therapies; and preventing arrangements that raise issues and concerns regarding patient safety or quality of care.

V. OPINION #2: CEPHALON MADE FURTHER COMPLIANCE ENHANCEMENTS BEFORE, AS PART OF, AND AFTER THE CIA

71. While "Cephalon had established a compliance program that meets the seven elements of effectiveness" set forth in OIG guidance prior to Cephalon's entry into the CIA, "[t]he CIA provided Cephalon with the opportunity to strengthen that program."[104] The requirements set forth in the CIA necessitated, among other changes, the introduction of the Standards of Global Business Practices (an international code of conduct),[105] re-branding the hotline and instituting a new phone number and email system for reporting any issues (including compliance-related issues),[106] reorganizing the Global Compliance Committee,[107] streamlining and updating numerous corporate and promotional policies, and hiring additional compliance professionals. Alongside these updates came additional

[104] Effectiveness of Cephalon's Global Compliance Program Board Update TEVA_MDL_A_04321682-87 (July 30, 2009).

[105] Standards of Global Business Practices ("Cephalon Code of Conduct"), TEVA_MDL_A_00552635-81 (2008).

[106] Reporting and Investigations of Misconduct (C-150), TEVA_MDL_A_00552585-88 (July 1, 2008).

[107] Charter of Cephalon's Global Compliance Committee, TEVA_MDL_A_00819644-45 (January 2009).

training, monitoring, and auditing programs as well as a continued commitment to the investigation and enforcement of circumstances constituting noncompliance.[108]

A. Restructuring of Corporate Compliance Framework

72. To ensure effective implementation of the CIA's requirements, Cephalon instituted an extensive framework to regulate all aspects of the company's business units and deter employees from violating relevant laws, regulations, procedures, and policies. Though it had already established a Chief Compliance Officer and Compliance Committee (meeting the OIG's Guidance's recommendation), Cephalon went further in late 2007 by creating a reconstituted Global Compliance Department ("Compliance"). This department was tasked with supporting the corporate compliance scheme, monitoring adherence to the CIA, and hiring four new compliance professionals.[109] In addition, Cephalon reorganized its Global Compliance Committee by adding new members that more broadly represent the company as a whole.[110] It also redesigned the PDRC in 2008, which was later renamed the PARC.[111]

73. In addition, in 2009, the Cephalon Activity Review and Evaluation ("CARE") committee was formed. This is a cross-functional team responsible for reviewing and evaluating initiatives, concepts, programs, and other activities involving healthcare professionals, to

[108] Effectiveness of Cephalon's Global Compliance Program Board Update, TEVA_MDL_A_04321682-87 (July 30, 2009).

[109] 2008 Global Compliance Report, TEVA_MDL_A_00360420-52 (January 28, 2009); Effectiveness of Cephalon's Global Compliance Program Board Update, TEVA_MDL_A_04321682-87, at TEVA_MDL_A_04321683 (July 30, 2009).

[110] 2008 Global Compliance Report, TEVA_MDL_A_00360420-52 (January 28, 2009), at TEVA_MDL_A_00360421.

[111] Supra ¶ 36.

ensure these activities met the requirements set forth in the Company's U.S. Sales and Marketing Policy (GPO-100) and other relevant company policies and procedures.[112] Core functions represented include the marketing, compliance, medical, and legal departments. The CARE committee's Operations Procedure was set forth in Cephalon's GPO-114,[113] and then in Teva's U.S. Policy-115.[114] Most notably, the CARE committee focuses on reviewing activities such as: Speaker bureaus; Speaker training; Advisory boards; Consultant arrangements; Symposia; and Service arrangements with healthcare institutions or organizations.[115] Among other information, any application to CARE committee needs to (i) "describe the actual, bona fide and objective business need," and (ii) "[i]nclude the total compensation to be paid for the services and the factors influencing the determination of fair market value."[116]

B. Modification of Written Policies to Meet Additional CIA Requirements

74. Cephalon revised its pre-existing written policies and implemented several new policies and procedures in response to requirements set forth in the CIA. For instance, the 2009 "Speaker Bureau Management Procedure" reiterates that all speakers must go through a

[112] Cephalon Activity Review & Evaluation (CARE) Process (GPO-114), TEVA_MDL_A_00552037-41 (Jan. 26, 2009).

[113] Id.

[114] *See* Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560898 (July 1, 2012)

[115] Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560898 (July 1, 2012).

[116] Cephalon Activity Review & Evaluation (CARE) Process (GPO-114), TEVA_MDL_A_00552037-41, at TEVA_MDL_A_00560899 (Jan. 26, 2009).

mandatory compliance training that specifically educated HCPs on the FDA promotion regulations.[117]

75. In 2012, after the acquisition of Cephalon by Teva USA, Teva USA implemented two policies related to educational grants, honoraria, and support. The "Independent Medical Education Grant Policy" emphasizes that it is impermissible for any Teva USA personnel or agent to control any aspect of an independent education activity and that grant support is independent of considerations of product promotion or sales.[118] The 2012 policy on "Payments to Healthcare Professionals Involved in Scientific and Medical-Related Activities" sets forth criteria for hiring an HCP based on medical expertise, not prescribing potential. These criteria are primarily focused on ensuring that the HCP is providing an actual, bona fide and objective business need.[119]

76. Cephalon's policy on the submission of medical requests also is supplemented by the pre-existing policy for Teva USA. The latter mandates that "[i]t is Teva's policy that sales representatives and other employees not solicit, either directly or indirectly, any questions from healthcare professionals ('HCPS') regarding off-label uses of Teva products. Sales representatives may not respond to any requests from HCPs for information about off-

[117] Speaker Bureau Management Procedure, TEVA_MDL_A_00953748-54 (Jan. 26, 2009).

[118] "Independent Medical Education Grants (US Policy-205)," in Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560932 (July 1, 2012).

[119] Payments to Healthcare Professionals Involved in Scientific and Medical-Related Activities (US Policy 260), in Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560943-44 (Sep. 17, 2012) ("Teva only seeks the services of adequately qualified HCPs for a sound business need or reason and always pays fair-market value for the services rendered. The same principles apply to our interactions with other organizations involved in scientific clinical or medical research sponsored or supported by Teva. ... The Healthcare Professional is: selected based on their qualification to render the services. [S]elected by Teva personnel qualified to assess the healthcare professional's expertise")

label uses of Company products, but must instead refer such inquiries to Teva U.S. Medical Information Department."[120]

77. Furthermore, Cephalon's pre-existing policy on reimbursement and prior authorization was further reaffirmed in the 2009 Cephalon "U.S. Sales and Marketing Policy" and in Teva USA's 2012 "Integrity Principle Policy." These policies further instruct that "it is never appropriate for a sales representative to suggest a code, diagnosis, or reimbursement strategy."[121]

C. Instituting Additional Training Programs

78. Cephalon developed a number of additional training programs after entering into the CIA in order to ensure employee adherence to new requirements and industry best practices.

79. In 2009, Cephalon instituted a new-hire training aiming to comply with the CIA as well as with the Anti-Kickback Law, the False Claims Act, FDA Promotional Regulations, PhRMA Code, and OIG Guidelines. Company representatives informed new employees that Cephalon's sales and marketing policy was governed by two guiding principles: (1) We don't buy business; and (2) Our promotional messages are always on-label, truthful and fair-balanced.[122]

[120] Submission of Medical Requests (US Policy-215), TEVA_MDL_A_00553161-62 (July 1, 2012).

[121] US Sales and Marketing Policy, TEVA_MDL_A_00552730-65, at TEVA_MDL_A_00552762 (Jan. 2009); Teva Integrity Principle, TEVA_MDL_A_00553193-217 (2012).

[122] Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance, TEVA_MDL_A_00801578-603, at TEVA_MDL_A_00801594 (Jan. 21, 2009).

80. In the following year, Cephalon added a new element to its new hire training regarding the company's philosophy on HCP targeting and call activity.[123] Cephalon made clear to new hires that the sales force was only to call on an HCP when it is "reasonable to believe that his or her practice includes patients that could be treated with a Cephalon product for an on-label indication, and, based on the nature of the HCP's practice, it is likely that he or she would treat the on-label condition."[124]

81. Lastly, in 2013, the company built in an assessment component of its new hire training that included modules on integrity principles, delivering promotional messages, interacting with HCPs, and ensuring scientific integrity, each of which required participants to score 80 percent or higher in order to receive credit.[125]

82. Cephalon's commitment to ensuring employee compliance extended beyond new hires. Updates to experienced employee training included the following new courses: a Standards Course, a Conflicts of Interest Course, a Promotional Practices Course, a DDMAC/FDA Regulations Course, Compliance Overview, and Home Study.[126] All U.S. employees took the "Standards Course" and a "Conflicts of Interest Course." As a supplement, the sales force took a "Promotional Practices" course, designed to provide employees with information about the regulatory environment, product promotion,

[123] Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance, TEVA_MDL_A_00381967-89, at TEVA_MDL_A_00381984 (Jan. 20, 2010).

[124] Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance, TEVA_MDL_A_00381967-89, at TEVA_MDL_A_00381984 (Jan. 20, 2010). Emphasis in the original.

[125] Integrity In Focus: Products and Promotion, TEVA_MDL_A_00772936-149, at TEVA_MDL_A_00772949 (August 15, 2013).

[126] List of CIA-Required Trainings Attended by Company Employees as of 9/30/2009 – Reported to the OIG in CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00561908 (2009).

interaction, hiring health care professionals, non-promotional interactions, and challenges. The lowest completion rate for a required training in any given year during the five-year reporting period under the CIA was 96 percent.[127]

83. Based on a review of training materials, one area of particular importance emphasized within both new hire and existing employee trainings was adhering to anti-kickback statues. For example, in a 2009 presentation, representatives were trained on the anti-kickback statute. The training included the basic elements of the anti-kickback statute, and provided additional information on the penalties associated with violations of the anti-kickback statute. The presentation also lists settlements within the pharmaceutical industry that involved pricing and kickback allegations in order to show the magnitude and severity of violations of the anti-kickback statute.[128] The presentation makes clear that Cephalon does not buy business, and provides additional information on the company's policies about payments to physicians.[129] These additional trainings and other compliance updates described above evidence that the CIA brought compliance to the forefront of nearly every function within the company.

[127] Within each CIA Annual Report Tab 5 provides a summary of the trainings provided pursuant to the CIA, as well as reports on completion percentages for employee training required by the CIA.

[128] InVentiv Health Care Compliance Training Interactions with Health Care Professionals, TEVA_MDL_A_11426483, pp. 39-44, (2009).

[129] InVentiv Health Care Compliance Training Interactions with Health Care Professionals, TEVA_MDL_A_11426483, pp. 8-9, (2009).

VI. OPINION #3: CEPHALON SUCCESSFULLY PASSED INDEPENDENT AUDITS REGARDING SALES AND MARKETING PRACTICES PURSUANT TO THE CIA.

84. Cephalon hired independent third parties to carry out audits of its relevant functions as mandated by the CIA and by the OIG Guidelines. The results from these audits and any follow-up action were reported in the annual OIG reports. The reports and Cephalon internal documents show that Cephalon satisfied all of the audit requirements imposed by the OIG. It is important to note that Cephalon had ceased promotion of Actiq well before the five-year CIA period, and has not promoted it since.

A. Independent Review Organization

85. Cephalon retained Ernst & Young LLP ("EY") to serve as the IRO from 2008 to 2014.[130] EY has a sterling reputation serving as the IRO for numerous CIAs. EY evaluated Cephalon's policies, procedures, and training, in addition to conducting analyses designed to identify potential off-label promotion and kickbacks. For each Reporting Period, EY presented its findings and recommendations to the OIG in the Annual IRO Report: Procedures, Findings and Recommendations. EY made three recommendations with respect to off-label information throughout the five years of auditing: (1) that "the Medical Sales Liaison Goals and Metrics document for each therapeutic area be updated to reflect the same emphasis the Medical Science Liaison Program policy reflects with respect to quality discussions as off-label, when necessary, and emphasizes the

[130] Report on Independent Review Organization's Engagement, TEVA_MDL_A_02939244-340, at TEVA_MDL_A_02939249 (September 30, 2009).

importance of balanced discussion with respect to product labeling;"[131] (2) that standard response letters to physicians, if available, be issued for all medical inquiries; and (3) that "Unique Response" letters should identify whether the information provided addresses an indication that is part of an approved product label.[132] All five annual reports were submitted to the OIG for review.[133] There is no evidence that the OIG took corrective action against Cephalon based on these reports and I have not seen anything to suggest that corrective action was necessary or would have been warranted.

B. Reportable Events

86. As mentioned above, the CIA required that Cephalon report "Reportable Events" to the OIG. "Reportable Events" were defined as anything that involved "matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized."[134]

87. The Reportable Events sections of the CIA annual reports did not document any incidents specific to Fentora, and, as noted above, Cephalon ceased promoting Actiq by the end of 2006.

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[131] CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00562009 (Nov. 20, 2009).

[132] Id.

[133] Report on Independent Review Organization Engagement Procedures, Findings and Recommendations," CIA Annual Report Year 2, TEVA_MDL_A_00562291-2861, at 00562430 (2010); CIA Annual Report Year 3, TEVA_MDL_A_00562862-3431 (2011); CIA Annual Report Year 4, TEVA_MDL_A_00560833-1763 (2012); CIA Annual Report Year 5, TEVA_MDL_A_00559116-998 (2013).

[134] CIA, § III.H.

C. Field Force Monitoring Program

88. Cephalon compliance personnel conducted 30 full-day "ride-alongs" every year and reported observations to the OIG.[135] Incidence reports were compiled annually to properly record that potential issues were investigated appropriately. The 2009 "Global Compliance Incident Details Report" includes one reference to Fentora indicating that a "[Pain Care] sales representative called on a FENTORA [Do-Not-Call] HCP multiple times." This incident was noted during the monitoring activities and followed up by a written warning.[136]

89. The annual reports sent to the OIG show that any instance of potential promotional issues occurred in rare occasions. When Cephalon became aware of one of these occurrences, it took corrective action. For example, the first annual report documented two incidents of noncompliance for drugs other than Actiq or Fentora, and, in response, Cephalon took corrective action that included employment termination.[137] No instances of non-compliance related to Fentora were identified in the annual reports.

D. Message Recall Monitoring Program

90. Cephalon hired ZS Associates, a well-known analytic firm retained extensively by pharmaceutical companies, as an independent entity to analyze HCP recall of the marketing messages delivered by members of the sales force. During two one-week

[135] Field Force Ride-Along Program (GC-220), TEVA_MDL_A_00552273-75 (Jan. 26, 2009).

[136] 2009 Global Compliance Incident Details Report, TEVA_MDL_A_00769186 (2009) (produced natively as an Excel spreadsheet – refer to last two tabs only).

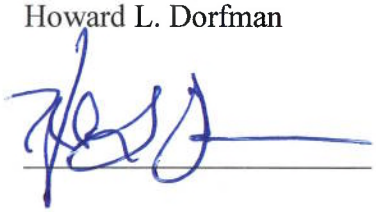
[137] Summary of Field Force Monitoring Program," September 30, 2009, CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290.

VII. CONCLUSIONS

Industry practice has undergone significant changes since 2003 and so has the focus of compliance regulators. These developments can be examined by reviewing the various corporate integrity agreements and other enforcement methods (e.g., enforcement letters issued by the FDA to various pharmaceutical companies). Since at least 2003, Cephalon took actions to comply with OIG guidelines and, by at least 2006, had a robust compliance system in place that met or exceeded OIG guidelines. That compliance system was further enhanced by Cephalon's actions and compliance with the CIA.

Signed on the 10th day of May, 2019.

Howard L. Dorfman



Appendix A

Curriculum Vitae

HOWARD L. DORFMAN
14 Haggerty Drive
West Orange, NJ 07052
(862) 252-9824 (H)
(203) 464-0634 (C)
hldorfman@gmail.com
www.linkedin.com/in/howard-dorfman

H. L. DORFMAN PHARMACEUTICAL CONSULTING, LLC, New Jersey, New York
(September 2015 to present)

A consulting resource to the pharmaceutical, biotech and medical device industries and healthcare law firms focusing on identifying and addressing issues that impact current business practices. Focus is on the most significant issues affecting these industries including corporate governance, healthcare and SEC compliance, FDA regulatory requirements, risk management processes and litigation. Highly experienced in creating and auditing company compliance programs, establishing internal training programs, negotiating state and federal insurance and reimbursement agreements, and structuring settlements relating to government compliance violations. In addition, responsible for establishing processes for review and approval of FDA-compliant advertising and promotional materials. Experience includes supporting the needs of start-up companies as well as established entities in the healthcare field in negotiating and drafting licensing, research, manufacturing, marketing and distribution agreements. Particular expertise in advising on complex commercial transactions, M&A/joint ventures, creating effective due diligence teams, conducting in-depth review of current SOPs and company practices, and designing remedial programs to reduce corporate exposure in compliance, regulatory and litigation matters with in-house personnel.

EDGE THERAPEUTICS, INC., *New Jersey (February 2017 to August 2018)*

Senior Corporate Counsel at a publicly-listed clinical-stage biotechnology company involved in the discovery, development and commercialization of novel, hospital-based therapies in the management of acute, life-threatening neurological and other conditions. Responsible for the development of the company's first healthcare compliance function, including drafting all compliance-related policies and procedures for all personnel levels and departments including marketing, sales, research & development, manufacturing, Q/C, clinical, and C-suite management. In addition, responsible for development of the promotional review committee and Investigator Trial process, and drafted contract templates for company-healthcare professional agreements (including those relating to consulting activities, advisory boards, and Investigator Initiated Trials). Legal work included negotiating and drafting corporate contracts and advising corporate officers and Board of Directors of developing legal and compliance issues affecting the pharmaceutical and biotechnology industries.

TURING PHARMACEUTICALS LLC, *New York, New York (December 2014-August 2015)*

Senior Vice President, General Counsel of the U.S. operations of a privately-held, Swiss-based pharmaceutical and biotech company focusing on the development and commercialization of a wide range of therapies for orphan diseases and other unmet medical needs. As general counsel following the company's founding in October 2014, I was responsible for supervising all legal activities including raising capital, crafting a company stock option plan, building an in-house legal department and network of outside counsel, provide legal counsel for M&A and joint venture activities, craft required standard operating procedures as well as a promotional review function, and serving as interim Chief Compliance Officer and develop a compliance blueprint for the company.

FERRING PHARMACEUTICALS INC., *Parsippany, New Jersey (June 2011-November 2014)*

Vice President, General Counsel and Corporate Secretary at Ferring Pharmaceuticals Inc., the U.S.-based subsidiary of Ferring Holding, a research based pharmaceutical, medical device and biotech company based in St. Prex, Switzerland. Responsible for all legal matters relating to the company's U.S. operations. Focus on FDA regulatory, health care compliance and risk management with emphasis on issues relating to food and drug law, product liability, compliance, clinical trials and corporate transactional work (M&A). Created a cross-functional team with the IP group and supervised IP-related litigation, and served as legal counsel to the R&D function, which included negotiating and drafting clinical trial agreements.

H. L. DORFMAN & ASSOCIATES CONSULTING SERVICES, *Connecticut and New York (February 2011- June 2011)*

President of consulting company specializing in providing FDA regulatory, health care compliance, and risk management advice to pharmaceutical, medical device, and biotech companies. Primary focus on developing and managing regulatory, compliance and liability audits and crafting remediation and risk management programs and processes pre- and post-FDA approval, negotiating settlements with federal and state authorities, draft policies and procedures for implementation of Corporate Integrity and Deferred Prosecution Agreements. Concentration on providing guidance on regulatory and compliance requirements during entire product life cycle from pre-clinical and Phase I-III trials through regulatory submissions, commercialization (including advertising and promotion reviews and manufacturing oversight), and post-approval obligations.

ROPES & GRAY, LLP, *Counsel, New York, New York (2008- 2011)*

Counsel in the Life Sciences Group at Ropes & Gray in New York; practice focused on complex issues relating to the pharmaceutical, medical device and biotech industries including compliance management, fraud and abuse and regulatory law. Major areas of expertise include FDA regulatory law, fraud and abuse, compliance programs, risk management processes, M&A, corporate governance, licensing and antitrust. Counselled pharmaceutical, biotech and medical device manufacturers on reducing potential liability exposure.

BAYER PHARMACEUTICALS CORPORATION, *Vice President, Assistant General Counsel, West Haven, Connecticut (2001- 2008)*

Counseled on Mergers and Acquisitions, Corporate Governance, Licensing and Antitrust matters, provided strategic guidance across business units and functional groups in Compliance Management, Fraud and Abuse and FDA regulatory law, and responsible for coordination of company's risk management processes (Regulatory, Labeling, Drug Safety and Litigation) to identify and reduce potential for regulatory action and product liability exposure

BRISTOL-MYERS SQUIBB COMPANY, *(New York/New Jersey 1978-2001)*

Counsel, U.S. Medicines Group (1997-2001)

Responsible for the legal and compliance functions for the two largest prescription pharmaceuticals in the BMS cardiovascular franchise including all aspects of regulatory compliance, antitrust analysis, and contract and grant review and approval. Served as Compliance counsel for U.S. Medicines sales and medical communications functions and responsible for the legal and regulatory work for the medical device division (Edward Weck & Company) including development of the cGMP policies, development of regulatory compliance SOPs, and negotiated a major product recall with the FDA.

As Counsel in the Litigation group, directed nationwide mass tort litigation involving hormone (DES), antibiotic (tetracycline), and medical device (silicone implant) products

KNYPER, BARTFIELD, FIORIE, SCHAERF & MASSARO,
Senior Associate, New York, New York (1975-1978)

Senior associate with first-chair responsibility for medical malpractice and product liability trials and appeals

Teaching

Seton Hall University School of Law, Adjunct Professor, Visiting Distinguished Practitioner
Newark, New Jersey, Spring 2012, Spring 2013; Spring 2014, Spring 2015, Spring 2016, Spring 2017, Fall 2017 and Spring 2019 semesters- - Courses: Pharmaceutical and Medical Device Marketing and Compliance; Compliance and Enforcement in the Pharmaceutical Industry; Food and Drug Law; Compliance Skills

Publication

Pharmaceutical Compliance and Enforcement Answer Book 2014, 2015, 2016, 2017 and 2018 editions- Practicing Law Institute *(New York, New York)* (Editor and Co-author)

Education and Bar Admissions

Yeshiva University (BA); Brooklyn Law School (JD)
New York and New Jersey

Appendix B

Materials Considered

Court Documents

Deposition of John Hassler, In Re: National Prescription Opiate Litigation, MDL No. 2804, United States District Court for the Northern District of Ohio, Eastern Division, November 16, 2018, Exhibit 8.

Second Amended Cuyahoga Complaint, *In Re: National Prescription Opiate Litigation*, May 25, 2018.

Third Amended Summit Complaint, *In Re: National Prescription Opiate Litigation*, March 21, 2019.

Bates-Stamped Documents

"2004 Annual Compliance Update," TEVA_MDL_A_00667543-754.

"2004 Cephalon Code of Conduct," TEVA_MDL_A_09624030-698.

"2004 Mid-Year Compliance Update Memo," TEVA_MDL_A_06377159-81.

"2004 Sales Policy Handbook," TEVA_MDL_A_04794285-294.

"2006 Sales Policy Handbook," TEVA_MDL_A_01251767-77.

"2008 Global Compliance Report," TEVA_MDL_A_00360420-52.

"2009 Global Compliance Incident Details Report," TEVA_MDL_A_00769186.

"Cephalon Corporate Compliance Program," Teva_MDL_A_05508657.

"Centralized Activity Review and Evaluation (CARE) (US Policy-115)," TEVA_MDL_A_00560852-1167.

"Cephalon Activity Review & Evaluation (CARE) Process (GPO-114)," TEVA_MDL_A_00552037-41.

"Cephalon Newsletter (Summer 2005)," TEVA_MDL_A_08272952.

"Cephalon Speaker Bureau Policy," TEVA_MDL_A_00552396-420.

"CIA Annual Report Year 1," TEVA_MDL_A_00561764-2290.

"CIA Annual Report Year 2," TEVA_MDL_A_00562291-2861.

"CIA Annual Report Year 3," TEVA_MDL_A_00562862-3431.

"CIA Annual Report Year 4," TEVA_MDL_A_00560833-1763.

"CIA Annual Report Year 5," TEVA_MDL_A_00559116-998.

"Charter of Cephalon's Global Compliance Committee," TEVA_MDL_A_00819644-45.

"Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance," TEVA_MDL_A_00801578-603.

"Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance," TEVA_MDL_A_00381967-89.

"Corporate Integrity Agreement," TEVA_MDL_A_06380925-89.

"Cephalon Corporate Compliance Program," Teva_MDL_A_05508657.

"Effectiveness of Cephalon's Global Compliance Program Board Update," TEVA_MDL_A_04321682-87.

"Field Force Ride-Along Program (GC-220)," TEVA_MDL_A_00552273-75.

"Good Business Practice Field Guide (June 2008)," TEVA_MDL_A_00552305-63.

"Independent Medical Education Grants (US Policy-205)

"Integrity In Focus: Products and Promotion," TEVA_MDL_A_00772936-149.

"InVentiv Health Care Compliance Training Interactions with Health Care Professionals," TEVA_MDL_A_11426483.

"Marketing Policy Handbook," TEVA_MDL_A_00552840-49.

"Marketing Speaker Bureau (CSP) Policy (June 2007)," TEVA_MDL_A_00954145-69.

"Mid-Year Compliance Update," TEVA_MDL_A_06377159-81.

"Policy on Gifts, Meals, and Entertainment for Physicians and other Health Care Practitioners (October 2006)," TEVA_MDL_A_04756815-21.

"Policy on Promotional Materials and Activities," TEVA_MDL_A_01251780-89.

"Policy on Promotional Materials and Activities (March 2007)," Teva_MDL_A_06880605-14.

"Promotion and Advertising Review (PARC) Process SOP BM-RA-102," TEVA_MDL_A_00553140-49.

"Promotional Review Process," TEVA_MDL_A_00552513-25.

"Promotional Review Process Training," TEVA_MDL_A_08923233-98.

"Report on Independent Review Organization's Engagement," TEVA_MDL_A_02939244-340.

"Reporting and Investigations of Misconduct (C-150)," TEVA_MDL_A_00552585-88.

"Review and Approval of Promotional Materials," Teva_MDL_A_04785055-62.

"Speaker Bureau Management Procedure," TEVA_MDL_A_00953748-54.

"Standards of Business Conduct," TEVA_MDL_A_06880695-710.

"Standards of Global Business Practices ("Cephalon Code of Conduct")," TEVA_MDL_A_00552635-81.

"Submission of Medical Requests (US Policy-215)," TEVA_MDL_A_00553161-62.

"Teva Integrity Principle," TEVA_MDL_A_00553193-217.

"Teva Year 4 FENTORA Message Recall Surveys," TEVA_MDL_A_0561498-500.

TEVA_MDL_A_06616796-855.

TEVA_MDL_A_11892838-39.

TEVA_MDL_A_11892858-61.

TEVA_MDL_A_11892862-64.

TEVA_MDL_A_11892865-70.

TEVA_MDL_A_11892871-74.

TEVA_MDL_A_11892875.

TEVA_MDL_A_11892876-82.

TEVA_MDL_A_11892883-86.

TEVA_MDL_A_11892887-99.

TEVA_MDL_A_11892900-03.

TEVA_MDL_A_11892904-06.

"Training Process for Members of the Sales Organization (SOP-0001044)," TEVA_MDL_A_01249224-28.

"Understanding FDA Regulations," TEVA_MDL_A_02724063.

"U.S. Sales and Marketing Policy," TEVA_MDL_A_00552786-818.

"U.S. Sales and Marketing Policy," TEVA_MDL_A_00552730-65.

Public Documents

Misdeameanor Guilty Plea, *US v. Cephalon, Inc*., United States District Court for the Eastern District of Pennsylvania, September 15, 2008, available at https://www.justice.gov/civil/file/892071/download.

Office of Inspector General, "Compliance Program Guidance for Pharmaceutical Manufacturers," ("OIG Guidance"), 2003, https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.

Appendix C: List of Policies and Procedures Reviewed

Policy or Procedure Title	Company	Effective Date	Bates Number
Code of Conduct	Cephalon	Jan-00	TEVA_MDL_A_09624030
Cephalon Corporate Compliance Program	Cephalon	2000	TEVA_MDL_A_05508657
Guide for Discussions with Physicians	Cephalon	May-04	TEVA_MDL_A_02678395
Cephalon Speaker Bureau Policy	Cephalon	Jun-04	TEVA_MDL_A_00552396
Sales Policy Handbook	Cephalon	Oct-04	TEVA_MDL_A_04794285
Advertising and Promotional Materials and Activities	Cephalon	Oct-04	TEVA_MDL_A_11892858
Identifying Called on Universe of Physicians in Connection with Promotional Activities	Cephalon	Oct-04	TEVA_MDL_A_11892862
Gifts, Meals and Entertainment for Physicians and Other Healthcare Practitioners	Cephalon	Oct-04	TEVA_MDL_A_11892871
Promotional Meetings	Cephalon	Oct-04	TEVA_MDL_A_11892876
Perceptorship	Cephalon	Oct-04	TEVA_MDL_A_11892883
Funding to Support Independent Third-Party Educational or Scientific Meetings	Cephalon	Oct-04	TEVA_MDL_A_11892887
Grants or Support that Are not for Independent Medical Education	Cephalon	Oct-04	TEVA_MDL_A_11892900
Sample Management	Cephalon	Oct-04	TEVA_MDL_A_11892875
Employeee Reporting of Adverse Events, Product Complaints, Tampering Adulteration and/or Diversion	Cephalon	Oct-04	TEVA_MDL_A_11892904
Providing Reimbursement Information to Customers	Cephalon	Oct-04	TEVA_MDL_A_11892838
Medical Information Request Forms	Cephalon	Oct-04	TEVA_MDL_A_11892865
Grants or Support That Are Not For Independent Medical Education	Cephalon	Oct-04	TEVA_MDL_A_04794345
Policy on Advertising and Promotional Materials and Activities	Cephalon	Oct-04	TEVA_MDL_A_04794303
Standards of Business Conduct	Cephalon	Oct-04	TEVA_MDL_A_06880695
Code of Conduct	Cephalon	Feb-06	TEVA_MDL_A_00553166
Code of Business Conduct	Teva USA	Feb-06	TEVA_MDL_A_00553166

Appendix C: List of Policies and Procedures Reviewed

Policy or Procedure Title	Company	Effective Date	Bates Number
Training Process for Members of the Sales Organization	Cephalon	Apr-06	TEVA_MDL_A_01249224
Speaker Bureau Policy	Cephalon	Jun-06	TEVA_MDL_A_00552396
Sales Policy Handbook, with exhibits and Government Employee Certification Form	Cephalon	Oct-06	TEVA_MDL_A_00552850 - 52869
Policy on Gifts, Meals, and Entertainment for Physicians and other Health Care Practitioners	Cephalon	Oct-06	TEVA_MDL_A_04756815
Adverse Drug Experience, Product Complaint, and MIRF to PSMI	Cephalon	Oct-06	TEVA_MDL_A 00552829
Patient Safety	Cephalon	Feb-07	TEVA_MDL_A 00552453
Policy on Promotional Materials and Activities	Cephalon	Mar-07	TEVA_MDL_A_01251780
Promotional Materials and Activities	Cephalon	Mar-07	TEVA_MDL_A 00552870
Gifts, Meals, and Entertainment for Physicians and Other Healthcare Professionals	Cephalon	Mar-07	TEVA_MDL_A_00552891
Sample Management	Cephalon	Mar-07	TEVA_MDL_A_00552901
Preceptorships	Cephalon	Mar-07	TEVA_MDL_A_00553012
Promotional Meetings ("CSPs")	Cephalon	Mar-07	TEVA_MDL_A_00552995
Dissemination of Certain Off-Label Peer-Reviewed Reprints and Reference Textbooks (WLF Policy)	Cephalon	Mar-07	TEVA_MDL_A_00553033
Policy on Promotional Materials and Activities	Cephalon	Mar-07	TEVA_MDL_A_06880605
Medical Information Request Forms	Cephalon	Mar-07	TEVA_MDL_A_00552884
Marketing Policy Handbook	Cephalon	Jun-07	TEVA_MDL_A_00552840
Gifts, Meals, and Entertainment for Physicians and Other Healthcare Practitioners and exhibits	Cephalon	Jun-07	TEVA_MDL_A_00552905 - 552910
Developing Promotional and Advertising Materials	Cephalon	Jun-07	TEVA_MDL_A _00S57902
Grants and exhibits	Cephalon	Jun-07	TEVA_MDL_A_00552919 - 552933
Preceptorships and exhibits	Cephalon	Jun-07	TEVA_MDL_A 00552945 - 552969
Speaker Bureau (CSP)	Cephalon	Jun-07	TEVA_MDL_A_00552970
Interactions Among MSLs, Cephalon Business Personnel (e.g., Marketing) and HCPs	Cephalon	Jun-07	TEVA_MDL_A_00552942

Appendix C: List of Policies and Procedures Reviewed

Policy or Procedure Title	Company	Effective Date	Bates Number
WLF: Dissemination of Peer-Reviewed Reprints and Reference Text books and exhibits	Cephalon	Jun-07	TEVA_MDL_A00553036 - 553052
Marketing Speaker Bureau (CSP) Policy	Cephalon	Jun-07	Teva_MDL_A_0552396
Interactions Between MSLs, Business Personnel (e.g., Sales, Account Management, and Marketing) and Healthcare Professionals	Cephalon	Sep-07	TEVA MDL_A_00553057
Providing Reimbursement Information to Customers	Cephalon	Sep-07	TEVA_MDL_A_00553053
Third Party Grant Requests	Cephalon	Jan-08	TEVA MDL_A_00553030
Standards of Global Business Practices	Cephalon	Jan-08	TEVA_MDL_A_0052635
Good Business Practices Field Guide	Cephalon	Jun-08	TEVA_MDL_A_00552305
Reporting of Adverse Events, Product Complaints, and Suspected Diversions	Cephalon	Jul-08	TEVA_MDL_A_00552589
US Sales and Marketing Policy	Cephalon	Jul-08	TEVA_MDL_A_00552786
Reporting and Investigations of Misconduct	Cephalon	Jul-08	TEVA_MDL_A_00552585
Employee Conduct and Corrective Action	Cephalon	Jul-08	TEVA_MDL_A_00552247
Submission of Medical Requests	Cephalon	Jul-08	TEVA_MDL_A_00552687
US Sales and Marketing Policy	Cephalon	Jan-09	TEVA_MDL_A_00552730
Speaker Bureau Management Procedure	Cephalon	Jan-09	TEVA_MDL_A_00953748
Promotional Review Process	Cephalon	Jan-09	TEVA_MDL_A_00552513
Cephalon Activity Review & Evaluation (CARE) Process	Cephalon	Jan-09	TEVA_MDL_A_00552037
Targeting Assessment and Call Activity	Cephalon	Jan-09	TEVA_MDL_A_00552695
Medical Information and Monitoring	Cephalon	Jan-09	TEVA_MDL_A_00552427
Regulatory, Pharmacovigilance & Drug Safety Incident Management	Cephalon	Jan-09	TEVA_MDL_A_00552368
Standards of Behavior Policy	Teva USA	Jan-12	TEVA_MDL_A_00553159
Independent Medical Education Grants	Teva USA	Jul-12	TEVA_MDL_A_00560852
Centralized Activity Review and Evaluation (CARE)	Teva USA	Jul-12	TEVA_MDL_A_00560852
Integrity Principles Policy	Teva USA	Jul-12	TEVA_MDL_A_00553193
Reporting and Investigations of Misconduct	Teva USA	Jul-12	TEVA_MDL_A_00553150

Appendix C: List of Policies and Procedures Reviewed

Policy or Procedure Title	Company	Effective Date	Bates Number
Targeting Assessment and Call Activity	Teva USA	Jul-12	TEVA_MDL_A_00553163
Integrity Principle Policy	Teva USA	Jul-12	TEVA_MDL_A_00553193
Submission of Medical Requests	Teva USA	Jul-12	TEVA_MDL_A_00553161
Medical Information Request Monitoring	Teva USA	Jul-12	TEVA_MDL_A_00553125
Payments to Healthcare Professionals Involved in Scientific and Medical-Related Activities	Teva USA	Sep-12	TEVA_MDL_A_00560852
Promotional and Advertising Review Process	Teva USA	Feb-13	TEVA_MDL_A_00553140
Integrity In Focus: Products and Promotion	Teva USA	Aug-13	TEVA_MDL_A_00772936

Notes:

[1] Cephalon had various other policies with respect to pharmacovigilance and drug safety.